Amendment Under 37 C.F.R. 1.116 - Expedited Procedure
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REMARKS

In the Amendment and Response filed August 14, 2000, Applicants neglected to amend claim 1 to include the clarification that the claimed fragments include polypeptides of 15 or more contiguous amino acids of the polypeptide sequence of SEQ ID NO:1, as argued in the Remarks. The above amendment corrects that oversight, obviates the rejection under 35 U.S.C. § 102(a) and puts the claims in better condition for appeal.

In addition, Applicants request that new claims 21 and 22 be entered. These claims are dependent claims limited to polypeptides of SEQ ID NO:1 (and equivalents thereof), and compositions containing them. Applicants submit that these claims raise no new issues of patentability, and are presumed to be subject to the rejections under 35 U.S.C. §§ 101 and 112, first paragraph, regarding utility and enablement, set forth in the Final Office Action.

With respect to the remaining rejections under 35 U.S.C. §§ 101 and 112, first paragraph, including both utility and enablement as noted above, and the rejection for lack of written description which is presumed to relate solely to claims 1 and 11 (and not the newly added claims), Applicants traverse the rejections again, reiterating their previous remarks. Applicants note that the Examiner's "Response to Arguments" not only ignores the substance of Applicants' legal arguments ("Applicants assert that the Guidelines are themselves inconsistent with the law at pages 8-21. The Examiner will only address parts of this critique as it applies to the instant invention and rejection."), it also ignores Applicants' fully developed arguments, supported by sound reasoning and references showing same, regarding the very real-world, substantial, specific and credible utility of toxicology testing. Applicants in particular note that this utility is **specific** to detection of the claimed sequences (the claimed sequences will hybridize to only the same or almost identical sequences, not <u>all</u> sequences), is **substantial** in that it is a crucial part of many if not all drug development process used by pharmaceutical companies and thus has enormous public benefit, and it is certainly is **credible** to one of ordinary skill in the art (lack of credibility was not asserted in the Office Action).

It is clear that Applicants have not only disclosed in the specification a specific, substantial and credible utility, they have also established that it is a well-known utility have a very real-world application which is, in its presently available form, providing a substantial public benefit which the

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Examiner (and the Patent and Trademark Office as a whole) is apparently choosing to ignore at this time. Applicants will address that issue on Appeal.

The amended and newly added claims are submitted to raise no new issues of patentability, and to put the application in better condition for that Appeal. Therefore, entry of the amendments and new claims is submitted to be proper and is respectfully requested.

CONCLUSION

In light of the above amendments and remarks, Applicants submit that the present application is fully in condition for allowance, or at least better condition for Appeal, and request that the Examiner withdraw the outstanding rejections or at least enter the Amendments. Early notice to that effect is earnestly solicited.

If the Examiner contemplates other action, or if a telephone conference would expedite allowance of the claims, Applicants invite the Examiner to contact Applicants' Attorney at (650)855-0555.

Applicants believe that no fee is due with this communication. However, if the USPTO determines that a fee is due, the Commissioner is hereby authorized to charge Deposit Account No. **09-0108.** This form is enclosed in duplicate.

Respectfully submitted,

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Date: 21 Nov 2000

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